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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,649	03/01/2004	Franco Vallana	SBC1025USC1	9772

9561 7590 02/15/2006

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EXAMINER

GBERBI, SUZETTE JAIME J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 02/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/790,649	Applicant(s) VALLANA ET AL.	
	Examiner Suzette J. Gherbi	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/1/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/2/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment and response dated 1/18/06 has been received in application serial number 10/790,649. All comments have been taken into consideration.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 14-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular there is no mention in the specification for the newly added limitation of "*at a zero point of the sinusoidal shape of the annular element and a second end...at a zero point*".

Claim Rejections - 35 USC § 103

4.. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4, 7-19, 22-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang et al. 6,758,859 in view of von Oepen 6,193,747. Dang et al. discloses the invention as claimed noting figures 4-6 comprising: a stent with a radially expandable tubular body and an active agent for treatment of an implant site, the tubular body having an interior surface and an exterior surface; the tubular body having a plurality of sinusoidal shaped annular elements;, connected to at least one other annular element by a plurality of connection elements; each annular element and each connection element (24) having a rectilinear portion (strut 22) and a curved portion (upper 22 read col. 8, lines 36-41); the exterior surface of the tubular body having a plurality of recesses (30) positioned only in the rectilinear portions, the active agents being contained within the recesses. However Dang et al. does not specify that the connection portion is in the shape of a lambda or the specific percentage ranges of the recesses. Von Oepen teaches the stent structure with lambda shaped connection elements (noting figure 2b, element 7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the stent shape i.e.

lambda connection members because Dang et al. discloses in col. 3, lines 60-63 that the connecting elements may have a variety of shapes and patterns and is deemed a design modification. It is also obvious to one having ordinary skill in the art that the depots (30) of Dang et al. can encompass a variety of percent range coverage (see col. 6, lines 1-3, lines 12-17, lines 56-64, and col. 9, lines 11) in order to custom tailor the amount of thereapeutic substance to be released from the stent depending upon which part of the body is to be treated.

6. Claims 5-6, 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang et al. in view of von Oepen and further in view of Falotico et al. 20010029351. Dang et al. and von Oepen have been disclosed above however they do not specify the rectangular recess. Falotico et al. teaches that rectangular recesses for drug delivery are known in the art noting figure 2 element 106. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the depots of Dang into rectangular shapes because as noted above Dang discloses that a variety of depot configurations are envisioned in order to modify the drug release rate.

Response to Arguments

7. Applicant's arguments filed 11/18/05 have been fully considered but they are not persuasive. Applicant has amended claim 1 by removing subject matter which broadens the scope of the claim and has further amended claims 14, 29 and 31.

8. Regarding claim 1 applicant contends that that there is no motivation to modify the connectors of Dang yet admittedly applicant agrees that Dang does point out in the disclosure of pate 6,758,859 that Dang envisions utilizing a variety of shapes for the connectors. (noting col. 3, lines 60-63).

9. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation is derived from the fact that Dang does in fact state (noting col. 3, lines 60-63):

“.....the interconnecting elements 24 may also have a variety of shapes and **patterns** including, **but not limited to**, circular, oval, straight, curved etc.

Von Open has been utilized to *teach* that the shape of rectilinear and curved portions for connectors is well known in the art. Therefore the pattern can in fact be modified to have the “lambda” shape.

10. Regarding claim 14 there is no support for the newly added limitation of *at a zero point of the sinusoidal shape of the annular element and a second end...at a zero point*". It is also unclear as to exactly what the applicant is trying to claim by this limitation which is not described in the specification.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

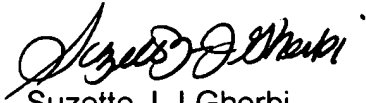
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Art Unit: 3738

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

A handwritten signature in black ink, appearing to read 'Suzette J-J Gherbi', written in a cursive style.

Suzette J-J Gherbi
08 February 2005